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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "American Recovery and Reinvestment Act "Developing a Registry of Registries"." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the Federal Register on February 23rd, 2012 and allowed 60 days for public comment. Several comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by (insert date 30 days after date of publication).

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by email at OIRA_submission@omb.eop.gov (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

American Recovery and Reinvestment Act "Developing a Registry of Registries"

The Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115, provided for the creation of a Clinical Trials Data Bank, known as ClinicalTrials.gov. Since its launch in 2000, the ClinicalTrials.gov system has registered over 90,500 trials. The large volume of studies currently listed in ClinicalTrials.gov and the high usage numbers suggest that the system has been successful at improving access to information about clinical studies. However,

while ClinicalTrials.gov supports the listing of observational studies, such listing is not required.

Patient registries are a distinct type of observational study. Patient registries may be designed for many purposes, such as to observe the natural history of disease, examine comparative effectiveness, or fulfill post-approval commitments. Patient registries have specific characteristics that are not currently captured on ClinicalTrials.gov. To date, some registry sponsors have attempted to leverage the observational study model to post patient registry-type records on ClinicalTrials.gov. However, stakeholders have noted that the system does not fully meet their needs.

Patient registries have received significant attention and funding in recent years. Similar to controlled interventional studies, patient registries represent some burden to patients (e.g., time to complete patient reported outcome measures, risk of loss of privacy), who often participate voluntarily in hopes of improving knowledge about a disease or condition. Patient registries also represent a substantial investment of health research resources. Despite these factors, registration of patient registries in ClinicalTrials.gov is not currently required, presenting the potential for duplication of efforts and insufficient dissemination of findings that are not published in the peer-reviewed literature. To ensure that resources are used in the most efficient manner, registries need to be listed in a manner similar to that of trials in ClinicalTrials.gov.

By creating a central point of collection for information about all patient registries in the United States, the Registry of Patient Registries (RoPR) helps to further AHRQ's goals by making information regarding quality, appropriateness, and effectiveness of health services (and patient registries in particular) more readily available and centralized.

The primary goal of this project is to engage stakeholders in the design and development of a RoPR database system that is compatible with ClinicalTrials.gov and meets the following objectives:

- 1) provides a searchable database of patient registries in the United States (to promote collaboration, reduce redundancy, and improve transparency);
- 2) facilitates the use of common data fields and definitions in similar health conditions (to improve opportunities for sharing, comparing, and linkage);
- 3) provides a public repository of searchable summary results (including results from registries that have not yet been published in the peer-reviewed literature);
- 4) offers a search tool to locate existing data that researchers can request for use in new studies; and serves as a recruitment tool for researchers and patients interested in participating in patient registries.

This study is being conducted by AHRQ through its contractor, the Outcome DECIDE Center, pursuant to the American Recovery and Reinvestment Act, Pub. L. 111-5, and pursuant to AHRQ's statutory authority to conduct and support research and

disseminate information on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to database development. 42 U.S.C. 299a(a)(1) and (8).

Method of Collection

To achieve the goals of this project the following data collections will be implemented:

- 1) Collect information from registry holders, defining a patient registry profile via a web-based interface, to populate the RoPR database system.

The purpose of the RoPR is to create a readily available public resource in the model of ClinicalTrials.gov to share information on existing patient registries to promote collaboration, reduce redundancy, and improve transparency in registry research. Patient registry research has become more prevalent and, based on stakeholder feedback, is not adequately served by ClinicalTrials.gov at present. The information being collected in the RoPR record will be visible to the public visiting the RoPR website and will be available for public use in this capacity.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden for the respondents' time to participate in the RoPR. Because the RoPR is a voluntary system available to any entity conducting a patient registry, it is not possible to determine the number of potential respondents. We do know that over 3,800 newly registered records designated as "observational studies" were entered into ClinicalTrials.gov in 2010. Only a subset of this number (which we will estimate at a maximum of 40%) would qualify as patient registries and would likely be registered in the RoPR. Therefore, we use 1,520 ($3,800 * 0.40$) in Exhibits 1 and 2 below as a very rough, but high, estimation of the potential number of respondents who will enter registries into the RoPR annually. The actual number of respondents will depend on a variety of factors and could vary widely. It should be remembered that mandates could evolve making registration in the RoPR mandatory. Our estimates therefore attempt to factor an upper threshold for volume.

Each respondent will enter a new RoPR record only once and is estimated to take 45 minutes. An estimated 50% (760 records) of RoPR records will be updated once a year and will take about 15 minutes. This estimate is based on a query of ClinicalTrials.gov which showed that about 50% of observational studies registered in ClinicalTrials.gov had been updated in the past year. The total respondent burden is estimated to be 1,330 hours annually.

Exhibit 2 shows the estimated cost burden associated with the respondent's time to participate in the RoPR. The total cost burden is estimated to be \$45,579 annually.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
New RoPR Record	1,520	1	45/60	1,140
Review/update RoPR Record	760	1	15/60	190
Total	2,280	na	na	1,330

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
New RoPR Record	1,520	1,140	\$34.27	\$39,068
Review/update RoPR Record	760	190	\$34.27	\$6,511
Total	2,280	1,330	na	\$45,579

*Based upon the mean average wage for Healthcare Practitioners and Technical Occupations, May 2010 National Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics. Available at:
http://www.bls.gov/oes/current/oes_nat.htm#29-0000.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost to the government to create and maintain the RoPR for 3 years. The total cost is estimated to be \$3,184,333.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	\$2,318,509	\$772,836
Project Management	\$409,149	\$136,383
Overhead	\$456,675	\$152,225
Total	\$3,184,333	1,061,444

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 5, 2012

Carolyn M. Clancy,
Director

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